



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 26 1999

6435 '99 MAR 29 P1:31

Mr. James A. Erickson
723 North 16th Place
Sturgeon Bay, Wisconsin 54235

Dear Mr. Erickson:

Thank you for your correspondence to Senator Herbert Kohl, regarding proposed new Food and Drug Administration (FDA or the Agency) regulations on statements made for dietary supplements concerning the effect of the product on the structure or function of the body. Senator Kohl has asked us to respond directly to you.

FDA published this proposed rule in the Federal Register on April 29, 1998. The comment period closed on August 27, 1998; however, FDA extended the comment period until September 28, 1998. FDA invited written comments on the proposal from the public and industry. All comments received will be reviewed and considered by the Agency in developing the final rule.

Your comments have been forwarded to the docket for this issue. While the Agency is under no legal obligation to consider comments received after the comment period, we do try to accommodate all comments as time and resources permit.

Enclosed is information which may be of interest to you. We hope this information has been helpful.

Sincerely,

Melinda K. Plaisier
for Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

Enclosure
April 24, 1998 HHS News release

cc: Dockets Management Branch
(Docket No. 98N-0044)

The Honorable Herbet Kohl
United States Senate
Washington, D.C. 20510

98N-0044-1

C22298/DWS



MAR 2 1999

Executive Secretariat Office
Food and Drug Administration
Fishers Lane Room 1670
Rockville, Maryland 20857

Dear Ms. Clarke:

The attached correspondence was received by the Health Care Financing Administration. Since it appears that the attached correspondence can best be evaluated by your office, we are referring correspondence to you for your consideration and appropriate action.

Sincerely,

Melba Miller

Mary Ann Troanovitch *for*
Director

Division of Correspondence
Control and Management

Enclosures

HERBERT KOHL
WISCONSIN

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United States Senate
WASHINGTON, DC 20510-4903

COMMITTEES:
APPROPRIATIONS
JUDICIARY
SPECIAL COMMITTEE
ON AGING

September 22, 1998

Ms Nancy-Ann DeParle
Administrator
Health Care Financing Administration
Room 314-G 200 Independence Ave S. W.
Washington, D.C. 20201-0004

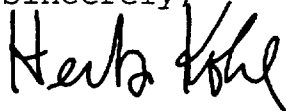
Dear Ms. DeParle:

I am writing to request your assistance in helping several of my Wisconsin constituents. Enclosed please find copies of their correspondences.

Any assistance you could provide in responding to these concerns would be greatly appreciated. Please respond directly to my constituents and send a copy to my office.

Thank you for your attention to this matter.

Sincerely,



Herb Kohl
U.S. Senator

HK:er

1998 SEP 23 PM 1:11
U.S. SENATE
LEGISLATIVE SECRETARIAT
WASHINGTON, D.C. 20540

No. 99-1514

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8-26-98

Honorable Herbert Kohl
US Senate
Washington, D.C. 20510

Dear Mr. Kohl:

I am writing to notify you that FDA's proposed rulemaking on structures/function claims, 21 CFR part 101/Docket #98N-0044, is **totally unacceptable** to me as an American consumer of dietary supplements. Any final rule must reflect the true meaning and intent, mandated by Congress, of the Dietary Supplement Health and Education Act (DSHEA).

I support the FDA's effort to fully implement DSHEA as intended by Congress, however, I strongly object to the proposed regulations which:

1. Limit my access to (scientific) information about dietary supplements and health, and
2. Redefine disease restricting my ability to focus on preventive care and wellness.

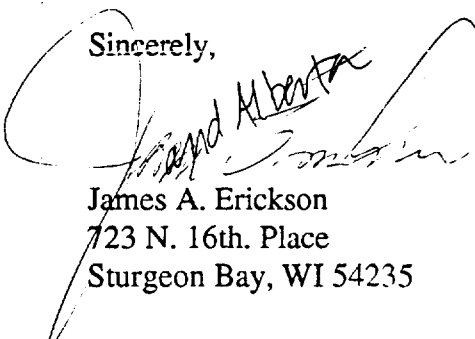
It is extremely important to preserve Section 6 of DSHEA to allow for a Robust flow of valuable health information in the marketplace.

I want free access to available information about dietary supplements and health, and I want FDA to withdraw its proposal to redefine disease in a way that limits such health information.

DSHEA allows products to make structure/function claims on the product labels. Redefining disease to nullify that part of DSHEA **must** be withdrawn.

I feel I have a **right** to make my own decisions about my health, and I don't need Big Brother to make those decisions for me.

Sincerely,



James A. Erickson
723 N. 16th. Place
Sturgeon Bay, WI 54235